AMENDED IN ASSEMBLY MARCH 31, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 1277

Introduced by Assembly Members Hill and Perea

February 18, 2011

~~An act relating to business.~~*An act to amend Sections 111550 and 111630 of the Health and Safety Code, relating to public health.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1277, as amended, Hill. ~~Biotechnology industry: regulation.~~ *Sherman Food, Drug, and Cosmetic Law*

(1) The Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices, and is administered by the State Department of Public Health. The law prohibits the sale, delivery, or giving away of any new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under specified provisions of the federal Food, Drug, and Cosmetic Act, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the federal act.

(2) The Sherman Food, Drug, and Cosmetic Law requires the department to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

This bill would revise the above described prohibition, as specified, and require the department to waive the fee for the issuance and renew

of a license for a person who has paid the most recent annual fees required pursuant to the federal act.

~~Existing law creates various state agencies and authorizes certain of those agencies to regulate the operations of businesses.~~

~~This bill would make findings and declarations of the Legislature and state the intent of the Legislature to adopt legislation that would reduce regulatory redundancies impacting the biotechnology industry.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 111550 of the Health and Safety Code is amended to read:

111550. No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is a new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355); *it is a new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262),* or it is a new device *that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360) and* for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug or in the case of a new device, a full statement of its composition, properties, and construction and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

SEC. 2. Section 111630 of the Health and Safety Code is amended to read:

111630. *(a)* The department shall by regulation establish the application form and set the fee for licensure and renewal of a license. The penalty for failure to apply for renewal of a license within 30 days after its expiration is ten dollars ($10) and shall be added to the renewal fee and be paid by the applicant before the renewal license may be issued. All moneys collected as fees shall be expended when appropriated by the Legislature in the carrying out ~~of the provisions~~ of this part and the regulations adopted pursuant to this part.

(b) Notwithstanding subdivision (a), the department shall waive the fee for the issuance and renew of a license for a person licensed pursuant to this section who has paid the most recent annual fees required pursuant to the federal act.

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(c) A person licensed pursuant to this section shall immediately notify the department of any change in the information reported in the license application.

~~SECTION 1. (a) The Legislature finds and declares both of the following:~~

~~(1) There are over 2,200 companies and more than 267,000 employees statewide in the biotechnology industry. It is imperative that government agencies do not unnecessarily hinder this unique California industry, which added 12,000 jobs between 2005 and 2009.~~

~~(2) According to the 2011 California Biomedical Industry Report, 68 percent of chief executive officers said they expected to expand the overall size of their workforce within California. For the first time in the report's 17-year history, nearly twice as many biomedical chief executive officers said they intend to~~

~~increase manufacturing within California, 41 percent, compared to out-of-state, 21 percent, over the next two years. In addition, 62 percent of chief executive officers surveyed said they expect to expand research and development within California.~~

~~(b) It is the intent of the Legislature to enact legislation that would reduce regulatory redundancies impacting the biotechnology industry in California.~~

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